510(K) SUMMARY

CHEETAH I.V.D.S.

510(k) Number K023370

Applicant's Name:

Cheetah Medical, Inc.
1201 Market Street, Suit 1600
Wilmington, Delaware 19801, USA
Tel: 1 (302) 571-1128 or
1 (302) 777-6571
Fax: 1 (302) 656-8865

Contact Person:

Ms. Sharon McGrenrey
Cheetah Medical, Inc.
1201 Market Street, Suit 1600
Wilmington, Delaware 19801, USA
Tel: 1 (302) 571-1128 or
1 (302) 777-6571
Fax: 1 (302) 656-8865

Date Prepared:

September 2002

Trade Name:

Cheetah I.V.D.S.
Model 2002P

Classification Name:

Programmable Diagnostic Computer

Classification:

Programmable Diagnostic Computers are class II devices (Product Code DQK).

Predicate Device:

The Cheetah I.V.D.S. is substantially equivalent to the Autocorr® Plus (#3404) Pulse Oximeter/ECG Monitor (BCI INTL., INC.), cleared under K981939.

Performance Standards:

No performance standards have been established for such a device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the Cheetah I.V.D.S. complies with the following voluntary standards:

- IEC 60601-1-2:1993
- CAN/CSA-C22.2 No.601.1.2-94 (R1999)
- CISPR 11:1997+A1:1999 class A

- FDA reviewer guidance for premarket notification submissions, November 1993: clauses 7(ii)(c)(1), 7(ii)(c)(2), 7(ii)(c)(3), 7(ii)(d), 7(ii)(f);
- EN60601-1:1990+A1:1992+A2:1995+A13:1996
- IEC 60601-1:1988+A1:1991+A2:1995
- UL 2601-1:1997
- CSA-C22.2 No 601.1

Intended Use / Indication for Use:

The Cheetah Integrated Vascular Diagnostic System (I.V.D.S.) is a non-invasive tool intended to detect blood wave front (BWF) delay.

Device Description:

The Cheetah I.V.D.S. is a portable, non-invasive, 4-Channel Cheetah - Blood Wave Front (BWF) detector, with an additional Time Marker channel. The Cheetah channel is intended to measure the time lag between the start of the blood wave front in the peripheral vascular system and the peak of the R-wave on the time marker signal.

The Cheetah I.V.D.S. consists of 2 finger probes, 2 toe probes and time marker leads placed on the subject's wrists and legs. The probes are connected to a computer that analyses and presents a print out of the pulse wave as it reaches the periphery.

In addition, the Cheetah I.V.D.S. comprises standard Laptop computer connected to conventional analog-to-digital converter, which is used for the analysis and presentation of the acquired data.

Substantial Equivalence:

The design of the Cheetah I.V.D.S. utilizes currently available technology found in legally marketed devices. The major difference between the new device and the predicate device is the addition of electronic circuits for detection of peripheral BWF (one for each limb) and addition of software that calculates and compares the time lags between the cardiac Time Marker and the BWF. Testing was done to ensure that the Cheetah I.V.D.S. will perform safely and accurately within the environment for which it is to be marketed.

Safety testing was conducted in accordance with the following guidance and standards: IEC 60601-1-2:1993; CAN/CSA-C22.2 No.601.1.2-94 (R1999); CISPR 11:1997+A1:1999 class A; FDA reviewer guidance for premarket notification submissions, November 1993: clauses 7(ii)(c)(1), 7(ii)(c)(2), 7(ii)(c)(3), 7(ii)(d), 7(ii)(f); EN60601-1:1990+A1:1992+A2:1995+A13:1996; IEC 60601-1:1988+A1:1991+A2:1995; UL 2601-1:1997 and CSA-C22.2 No 601.1. The results demonstrated that the Cheetah I.V.D.S. meets the relevant requirements of the abovementioned guideline and standards and that it performs within its specifications and functional requirements.

In addition, verification and validation testing was performed to evaluate the performance of the Cheetah software. Test results showed that the Cheetah software performs according to its specifications.

Finally, a clinical study was performed to verify that the Cheetah Time Marker is substantially equivalent to a legally marketed Autocorr Time Marker. Study results showed that using the same Time markers, there is no statistically significant difference between the automatically calculated time lag measurements of the Cheetah I.V.D.S. and the output of the Autocorr device.

Based on the technological similarity of the Cheetah to its predicate device, and following the evaluation of the differences between the systems, we conclude that the Cheetah I.V.D.S. is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2003

Cheetah Medical, Inc.
c/o Ms. Sharon McGrerey
1201 Market Street, Suite 1600
Wilmington, Delaware 19801

Re: K023370
Trade Name: Cheetah Integrated Vascular Diagnostic System (I.V.D.S)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: October 2, 2002
Received: October 8, 2002

Dear Ms. McGrerey:

This letter corrects our substantially equivalent letter of December 24, 2002, regarding the contact person and address.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023370

Device Name: Cheetah I.V.D.S

Indications for Use:

The Cheetah Integrated Vascular Diagnostic System (I.V.D.S) is a non-invasive tool intended to detect blood wave front (BWF) delay.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Cardiovascular

510(k) Number K023370

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)